K014302

510(k) Summary

[As required by 21 CFR 807.92(c)]

MAR 2 9 2002

Submitter's Name / Contact Person

Pisharodi Surgicals, Inc.
942 Wildrose Lane
Brownsville, TX 78520

Contact Person:
Madhavan Pisharodi, M.D.
Tel: 956-541-6725

General Information

Trade Name	UNIMAX Pedicle Screw System
Common Name	Pedicle Screw Spinal System
Classification	Class II (Orthopedic Devices Panel -Code 87, Product Code MNI) 21 CFR 888.3070 - Pedicle Screw Spinal System
Predicate	DYNA-LOK CLASSIC Spinal System, Medtronic Sofamor Danek USA (K001532)

Device Description

The UNIMAX Pedicle Screw System consists of plates, bolts, screws and washers and is used to build a spinal construct. The purpose of the UNIMAX System is to provide stabilization during the development of a solid spinal fusion. The system is available in a variety of sizes. The components and instruments needed for this system are described in the Surgical Technique Manual. The UNIMAX Pedicle Screw System components are made from titanium alloy (Ti-6Al-4V) conforming to ASTM standard F-136. The UNIMAX components will be provided non-sterile.

Intended Use / Indications

The Universal MultiAXis (UNIMAX™) Pedicle Screw System is intended to provide immobilization and stabilization of non-cervical posterior spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine:

(1) Degenerative spondylolisthesis with objective neurological impairment; (2) Fracture; (3) Dislocation; (4) Scoliosis; (5) Kyphosis; (6) Spinal tumor, and (7) Failed previous fusion (pseudoarthrosis)."

When used as a pedicle screw fixation system the UNIMAX Pedicle Screw System is indicated for skeletally mature patients: (a) having severe spondylolisthesis (Grades 3 and 4) of the fifth lumbar-first sacral (L5-S1) vertebral joint; (b) who are receiving fusions using autogenous bone graft only; (c) who are having the device fixed or attached to the lumbar and sacral spine (L3 and below); and (4) who are having the device removed after the development of a solid fusion mass.

Substantial Equivalence Comparison

The UNIMAX System is substantially equivalent to the following device with respect to intended use/indications, system components and materials:

DYNA-LOK CLASSIC Spinal System, Medtronic Sofamor Danek USA (K001532)

Summary of Studies

Biomechanical test results verify the design specifications and support substantial equivalence for the UNIMAX System. Test results support the safety and performance of the UNIMAX System for its intended use.

Conclusion

The data and information provided in this submission supports a substantial equivalence determination, and, therefore, 510(k) premarket notification clearance of the Pisharodi Surgicals UNIMAX Pedicle Screw System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Madhavan Pisharodi, MD
Pisharodi Surgical, Inc.
942 Wildrose Lane
Brownsville, Texas 78520

MAR 2 9 2002

Re: K014302
Trade Name: Universal MultiAXis (UNIMAX) Pedicle Screw System
Regulatory Number: 21 CFR 888.3070, 21 CFR 888.3070
Regulation Name: Pedicle Screw Spinal System, Spinal Interlaminal Fixation, Orthosis
Regulatory Class: II
Product Code: MNH, MNI
Dated: December 28, 2001
Received: December 31, 2001

Dear Dr. Pisharodi:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS / INTENDED USE STATEMENT

510(k) Number: K014302

Device Name: UNiversal MultiAXis (UNIMAX) Pedicle Screw System

Indications / Intended Use:

The Universal MultiAXis (UNIMAX™) Pedicle Screw System is intended to provide immobilization and stabilization of non-cervical posterior spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine:

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K014302